



The Vitamin Marketing Experts

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March 10, 1998

Dr. Elizabeth Yetley
Director of the Office of Special Nutritionals
Division of Programs and Enforcement Policy
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street
HFS-455
Washington, D.C. 20204

Dear Dr. Yetley:

Notice is hereby given pursuant to the requirements of Section 403(r)(6)(21 U.S.C. 343(r)(6) of the Federal Food, Drug and Cosmetic Act of statements of nutritional support which have been made on the label and/or in the labeling in connection with the marketing of the dietary supplement FAMILY ESSENTIALS™ WITH REFERENCE TO ANY CLAIM CONCERNING CHAMOMILE. FAMILY ESSENTIALS™ WITH REFERENCE TO ANY CLAIM CONCERNING CHAMOMILE was first marketed with these statements of nutritional support on Friday, March 6, 1998. The statements of nutritional support are as follows:

"*Chamomile* is added because it is one of the safest and most widely used herbs to soothe digestive muscles and calm nerves. Mothers will find that it has a wonderfully beneficial effect when added to a child's diet."

The *Chamomile* herb (latin name: *matricaria recutita*) has been cultivated for many centuries in Germany. *Chamomile* is known as the "herb of the sun" because its daisy like flowers reminded the ancient Egyptians of the sun. It is the oils and bioflavonoids from these flowers that have been known for centuries to help soothe digestion and calm nerves. Today, *Chamomile* is one of our nation's best selling herbs and a favorite tea.

Family Essentials™ for Juniors contains *Chamomile* that is standardized using one of its well known bioflavonoids, apigenin. The bioflavonoids of *Chamomile* have shown in recent research to contain anti-inflammatory properties and to possess muscle-relaxing effects especially notable in the smooth muscles of the digestive tract. *Chamomile* is recommended for use when the digestive tract is either cramping or irritated due to anxiety or stress.

Very truly yours,
MASON VITAMINS, INC.

Sonia C. Rodriguez
VP Marketing & Regulatory Affairs

97S-0162

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STUDIES FOR CHAMOMILE CLAIMS

Viola H. et al; "Apigenin, a component of *Matricaria recutita* flowers, is a central benzodiazepine receptors-ligand with anxiolytic effects" *Planta Med*, 61 (3) 213-216, 1995

Achterrath-Tuckerman U., et al, "Pharmacological Investigations with Compounds of *Chamomile* v. Investigations on the Spasmolytic effect of compounds of *Chamomile* and Kamillosan on the isolated guinea pig ileum" *Planta Med*, 39: 38-50, 1980

Gerritsen ME, et al.: "Flavonoids inhibit cytokine induced endothelial cell adhesion protein gene expression" *Am J Pathol*, 147 (2): 278-92, Aug 1995

Safayhi H, et al.; "Chamazulene: an antioxidant-type inhibitor of leukotriene B4 formation" *Planta Med*, 60 (5): 410-413 Oct 1994

Mann C and Staba EJ: "The Chemistry, Pharmacology and Commercial formulations of *Chamomile*" In: *Herbs, Spices and Medicinal Plants: Recent Advances in Botany, Horticulture and Pharmacology*, Vol 1 (Craker LE and Sime JE, eds.) *Oryx Press*, Phoenix, Arizona, 1986, 235-280.

Tyler VE: "Herbs of Choice: The Therapeutic Use of Phytomedicinals". *Pharmaceutical Products Press*, New York, 1994, 57-59

Foster S: "Herbal Renaissance" *Gibbs-Smith Publisher*, Salt Lake City, Utah, 1994 64-67.

Tyler VE: "The Honest Herbal" *Pharmaceutical Products Press*, New York 1993, 83-86

Weiss RF: "Herbal Medicine" *Ab Arcanum*, Gothenberg, Sweden, 1988, 1-11.

"*Matricaria flos*". European Scientific Cooperative on Phytotherapy (ESCOP) Monograph, October 1990.

Bradley PR, ed: *Matricaria flower*. In: "British Herbal Compendium" Vol 1. *British Herbal Medicine Association*, Bournemouth, Dorset, England 1992, 154-157